-1-

Claims

- 1. A method to induce an antitumor immune response in a potential or actual prostate tumor-bearing subject which method comprises administering to said subject a composition comprising an ingredient which is active to induce said immune response and is selected from the group consisting of
- at least one antigen overrepresented in the prostate gland or an immunologically effective portion thereof;
- an expression system capable of generating *in situ* said antigen; and
 an antiidiotypic antibody or an immunologically effective portion thereof which
 mimics said antigen.
 - 2. The method of claim 1 where in said antigen is a protein or peptide.
- The method of claim 2 wherein said protein or peptide is selected from the group consisting of prostate specific antigen (PSA), prostate specific membrane antigen (PSMA), prostatic acid phosphatase (PAP) and an immunologically effective portion thereof.
- 4. The method of claim 1 wherein said subject is afflicted with metastatic 20 prostate cancer.
 - 5. The method of claim 1 wherein said subject has been surgically treated to excise said tumor but is at risk for recurrence.
- 25 6. The method of claim 1 wherein said composition is administered to said subject prior to surgical excision of said prostate tumor.

- 7. The method of claim 1 wherein said subject is a potential prostate tumorbearing subject at risk for said tumor.
- 8. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises an ingredient which is active to elicit said immune response, is formulated for parenteral administration and is

an expression system capable of generating *in situ* an antigen overrepresented on the prostate gland with respect to other tissues or an immunologically effective portion thereof.

- 9. The vaccine of claim 8 wherein said antigen is selected from the group consisting of prostate specific antigen (PSA), prostate specific membrane antigen (PSMA), prostatic acid phosphatase (PAP) and an immunologically effective portion thereof.
- The vaccine of claim 8 wherein the antigen is encapsulated in a liposome or coupled to a liposome.
 - 11. The vaccine of claim 10 wherein said liposomes contain an adjuvant or are precipitated with alum.
- The vaccine of claim 8 which further includes at least one adjuvant capable of enhancing said antitumor immune response.
 - The vaccine of claim 12 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; Bacillus Calmette-Guerin (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines;

10

cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).

- 14. The vaccine of claim 8 wherein said expression system consists essentially of DNA encoding said antigen or said portion or wherein said expression system comprises a living expression vector.
 - 15. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in subject which comprises an ingredient which is active to elicit said immune response, is formulated for parenteral administration and is

an antiidiotypic antibody or immunologically effective portion thereof which mimics an antigen overrepresented on the prostate gland with respect to other tissues.

- 16. The vaccine of claim 15 wherein said antigen is selected from the group consisting of prostate specific antigen (PSA), prostate specific membrane antigen (PSMA), prostatic acid phosphatase (PAP) and an immunologically effective portion thereof.
 - 17. The vaccine of claim 15 wherein the antigen is encapsulated in a liposome or coupled to a liposome.
 - 18. The vaccine of claim 17 wherein said liposomes contain an adjuvant or are precipitated with alum.
- 19. The vaccine of claim 15 which further includes at least one adjuvantcapable of enhancing said antitumor immune response.

10

- The vaccine of claim 19 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).
- 21. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises at least one antigen which is active to elicit said immune response, is formulated for parenteral administration and comprises said at least one antigen being overrepresented on the prostate gland with respect to other tissues or an immunologically effective portion thereof, wherein said antigen is encapsulated in or coupled to a liposome.
- 15 22. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises at least two ingredients which are active to elicit said immune response and are formulated for parenteral administration, wherein each ingredient is selected from the group consisting of
- an antigen overrepresented on the prostate gland with respect to other tissues or an immunologically effective portion thereof;
 - an expression system capable of generating *in situ* said antigen or said portion; and an antiidiotypic antibody or an immunologically effective portion thereof which mimics said antigen.
- 23. The vaccine of claim 22 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP and an immunologically effective portion thereof.

Atty Dkt: 204372000300

- 5 -

- 24. The vaccine of claim 22 wherein the antigen is encapsulated in a liposome or coupled to a liposome.
- The vaccine of claim 24 wherein said liposomes contain an adjuvant or are precipitated with alum.
 - 26. The vaccine of claim 22 which further includes at least one adjuvant capable of enhancing said antitumor immune response.
- The vaccine of claim 26 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).
 - 28. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors which comprises an ingredient which is active to elicit said immune response, is formulated for parenteral administration, and comprises at least one immunologically effective portion of an antigen overrepresented on the prostate gland with respect to other tissues said portion being less than the complete antigen.
 - 29. The vaccine of claim 28 wherein said antigen is selected from the group consisting of prostate specific antigen (PSA), prostate specific membrane antigen (PSMA), prostatic acid phosphatase (PAP).

20

Atty Dkt: 204372000300

- 6 -

- 30. The vaccine of claim 28 wherein said portion is encapsulated in a liposome or coupled to a liposome.
- The vaccine of claim 30 wherein said liposomes contain an adjuvant or are precipitated with alum.
 - 32. The vaccine of claim 28 which further includes at least one adjuvant capable of enhancing said antitumor immune response.
- The vaccine of claim 32 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; Bacillus Calmette-Guerin (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).
 - 34. A pharmaceutical or veterinary vaccine for eliciting an antitumor immune response to prostate tumors in a subject which comprises an ingredient which is active to elicit said immune response, is formulated for parenteral administration, and comprises
 - at least one antigen overrepresented on the prostate gland with respect to other tissues with the proviso that said antigen is other than human prostate specific antigen (PSA) in a form which is produced in human cells.
- 35. The vaccine of claim 34 wherein said antigen is PSA recombinantly produced in nonhuman cells and exhibits posttranslational modifications different from those of PSA produced in human cells.

- 36. The vaccine of claim 34 wherein said antigen is selected from the group consisting of PSA, PSMA, PAP and an immunologically effective portion thereof.
- The vaccine of claim 34 wherein the antigen is encapsulated in a liposome or coupled to a liposome.
 - 38. The vaccine of claim 37 wherein said liposomes contain an adjuvant or are precipitated with alum.
- The vaccine of claim 34 which further includes at least one adjuvant capable of enhancing said antitumor immune response.
- 40. The vaccine of claim 39 wherein said adjuvant is selected from the group consisting of Freund's complete adjuvant; alum; lipid A; monophosphoryl lipid A; *Bacillus*15 *Calmette-Guerin* (BCG) or other bacteria; polysaccharides; saponins; detoxified endotoxin (DETOX); muramyl tripeptide or muramyl dipeptide or their derivatives; SAF1; lymphokines; cytokines; colony stimulating factors; nonionic block copolymers; and immune stimulating complexes (ISCOMS).